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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,950	12/29/2004	Alexis Collette	263996US2XPCT	7363
22850 7590 11/01/2007 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER NEGIN, RUSSELL SCOTT	
			ART UNIT 1631	PAPER NUMBER
			NOTIFICATION DATE 11/01/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/519,950	Applicant(s) COLLETTE ET AL.	
	Examiner Russell S. Negin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-90 is/are pending in the application.
4a) Of the above claim(s) 57-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/7/2005; 5/9/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 14 August 2007 is acknowledged. The traversal is on the ground(s) that there is not undue search burden in examining all of the groups. This is not found persuasive because search burden is not a requirement for a lack of unity resulting from the national stage entry of an international application.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 46-90 are pending in the instant application, and claims 46-56 are examined.

Claims 57-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 August 2007.

Comments

Three preliminary amendments have been filed in the instant application on the following three dates: 31 January 2005, 26 September 2005, and 27 February 2006.

Applicant filed amendments to the specification, claims, and drawings on 31 January 2005. Of these amendments, the amendments to the drawings are not compliant with 37 CFR 1.121 because they do not include a full description of the

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changes made from the initial set of drawings to the amended set. The MPEP states in section 714 II D:

An explanation of the changes made must be presented in the "Amendments to the Drawings" or the remarks section of the amendment document.

Applicant's amendments filed on 26 September 2005 include amendments to the specification. Specifically, the amendment to the abstract is not in compliance with 37 CFR 1.121 because a marked up version of the abstract is not included.

Applicant's amendments filed on 27 February 2006 correct for a "Notice for Defective Response" issued on 27 January 2007 regarding sequence listings.

Specification

The disclosure is objected to because of the following informalities:

While there are 125 Figures in the instant set of drawings filed on 31 January 2007, the brief description of the Drawings on pages 10-15 only contains descriptions for Figures 1-27. Rule 37 CFR 1.74 requires a brief description for every figure in the application.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 47-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility". Note that the text of the Guidelines is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result.

In the instant case, the claimed invention does not "transform" an article or physical object to a different state or thing because it is a method for high throughput analysis of data sets. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial

exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

The question is thus whether the final result achieved by the claimed invention satisfies all three criteria of being useful, and concrete, and tangible.

Furthermore, the useful, tangible, and concrete result must be recited in the claim itself, rather than addressed in specification.

(2) **"TANGIBLE RESULT"** The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. The opposite meaning of "tangible" is "abstract."

The instant claims are drawn to a method for high throughput analysis of data sets. However, as claimed, the method does not produce a tangible result. For example, the method as claimed may take place entirely within the confines of a computer or a human mind without any communication to the outside world and without using or making available for use, the results of the computation. Thus, the instant methods of the claims do not produce any tangible result.

Therefore, the final result achieved by the claimed invention does not satisfy all three criteria of being useful, and concrete, and tangible.

Claim Rejections - 35 USC § 101 and 35 USC § 112

INDEFINITENESS

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-53 provide for the process of high throughput analysis of data sets, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this process is actually practiced.

It is noted that while claims 47-52 recite steps, they are in the passive voice and therefore it is not clear which steps are actually intended.

NONSTATUTORY SUBJECT MATTER

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 46 and 53 is rejected under 35 U.S.C. 101 because the claimed recitation of a process of high throughput data analysis, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 52 (line 2) and claim 55 (line 4), the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 53, line 1 recites "the method," where it is unclear if "the method" refers to "a method" earlier in the claim, or the method of claim 46.

Regarding claim 54, line 3 recites "purifying the DNA or RNA fragments." In this claim, it is unclear as to how a method of data analysis (as recited in claim 46, a claim from which claim 54 depends) results in the purification of DNA or RNA fragments.

Regarding claim 55, line 3 recites "on purified DNA or cDNA," where it is unclear if the antecedent basis is the synthesized cDNA of line 3 or another type of cDNA or DNA.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. 102(b) Rejection #1:

Claims 46-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Sotak et al. [Analytical Chemistry, 1983, volume 55, pages 782-787].

Claim 46 is drawn to a method for high throughput analysis of data sets generally described by sets of peaks characterized by a position and an area.

The study of Sotak et al. describes software for quantitative analysis by carbon-13 Fourier Transform Nuclear Magnetic Resonance Spectrometry. Tables II through IV on page 784 of Sotak et al. describe high throughput analysis of peak position and area for a mixture of chemicals.

Claim 47 is dependent from claim 46 with the additional limitation that bioinformatics tools are used to extract and smooth peak data sets according to parameter files and store them in data files.

Claim 48 is dependent from claim 46 with the additional limitation that particular profiles representing peaks are created to be analyzed.

Claim 49 is dependent from claim 46 with the additional limitation that a peak database is built.

Tables II through IV of Sotak et al. show the use of bioinformatics tools to extract peak data sets and store them as profiles in data files. The tables act as databases on page 784 of Sotak et al.

Claim 50 is dependent from claim 49 with the additional limitation that the peak database is analyzed by statistical tools.

The statistical tools used to analyze the peaks of Sotak et al. in Tables II through IV are the expected integral, the mean integral and the relative error.

35 U.S.C. 102(b) Rejection #2:

Claims 46 and 49-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Faure et al. [The Journal of Immunology, 1999, volume 163, pages 6511-6519]

Claim 46 is drawn to a method for high throughput analysis of data sets generally described by sets of peaks characterized by a position and an area.

The study of Faure et al. described the tolerance of T cells through various different mechanisms. Figure 3 of Faure et al. on page 6514 shows various peak positions and areas obtained through high throughput analysis.

Claim 49 is dependent from claim 46 wherein a peak database is built.

Figure 3 of Faure et al. illustrates a peak database.

Claim 50 is dependent from claim 49 with the additional limitation that the peak database is analyzed by statistical tools.

The arrows in Figure 3 of Faure et al. illustrate the analysis of the peak database by statistical tools.

Claim 51 is dependent from claim 50 with the additional limitation that analysis of the peak database is used to determine prognostic or diagnostic criteria.

Figures 1 and 2 of Faure et al. illustrate the effect of age on proliferation of cells in various organs of the test mice.

Claim 52 is dependent from claim 51 with the additional limitation that the prognostic and diagnostic criteria are used in the field of physiopathology.

Figures 1-3 of Faure et al. illustrate the physiopathology of T cell proliferation in mice.

Claim 53 is dependent from claim 46 with the additional limitation that the method is a high throughput method for analysis of immune repertoires.

Figure 3 of Faure et al. illustrate an immune repertoire analysis (i.e. V β 2, V β 6, and V β 13).

Claim 54 is dependent from claim 53 with the additional limitation of starting with biological samples, which contain DNA or RNA fragments, purifying the DNA or RNA fragments.

Claim 55 is dependent from claim 54 with the additional limitations:

- synthesizing cDNA from purified RNA;
- on purified DNA or cDNA, performing amplification of DNA by PCR or SDA methods by using oligonucleotides specific for antigen specific receptor genes ;
- on amplified DNA, performing a labeling for detection by performing a runoff extension step with J or C specific oligonucleotide labeled with a fluorescent drug;
- on each labeled amplified DNA, an electrophoretic separation is made on an automatic sequencer;
- for each electropherogram, identifying peaks by determining their position and area that correspond to labeled amplified DNA.

Claim 56 is dependent from claim 55 with the additional limitation that the method of analysis is based on reading of the labeled amplified DNA.

The top of column 2 on page 6512 of Faure et al. teaches RNA extraction and cDNA synthesis (i.e. instant claim 54 and the first part of claim 55).

The section in column 2 of page 6512 of Faure et al., entitled "Determination of the C κ -specific public T cell repertoire with immunoscope," (lines 15-45) anticipates the remainder of instant claim 55 and claim 56. Specifically, this passage of Faure et al. recites use of PCR on constant regions of the DNA, use of fluorescent tags to label amplified DNA, run-off reactions, and electrophoresis. Figure 3 of Faure et al. illustrates the results from electropherograms identifying peaks and illustrating their positions and areas.

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Conclusion

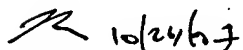
No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 10/24/07

RSN
24 October 2007

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.
PRIMARY EXAMINER